

CLAIMS

What is claimed is:

1. A system comprising at least one of the following:
  - a guide catheter comprising an occlusion device;
  - a delivery catheter comprising at least one occlusion device having a property to occlude a blood vessel without radially expanding the blood vessel, wherein the delivery catheter is received within the guide catheter; and
  - a guidewire comprising an occlusion device, wherein the guidewire is received within the guide catheter and/or the delivery catheter.
2. A kit comprising:
  - a delivery catheter comprising:
    - a shaft comprising a proximal end and a distal end and defining a delivery lumen through a portion thereof, the delivery lumen comprising a proximal end and a distal end;
    - a monitoring cannula defining a lumen therethrough, comprising a proximal end and a distal end, a portion of the monitoring cannula disposed within the shaft;
    - a port coupled to the distal end of the monitoring cannula;
    - a balloon inflation cannula defining a lumen therethrough, comprising a proximal end and a distal end, a portion of the balloon inflation cannula within the shaft;
    - a balloon adjacent to the distal end of the flexible shaft, the balloon comprising at least one material selected from the group consisting of polyether block amide resins, blends of polyether block amide resins, polyetheramides, a composite including an elastomeric material and EPTFE, a styrene-isoprene-styrene tri-Block co-polymer, and blends and mixtures thereof;
  - wherein the balloon is adapted to inflate to at least one of a predetermined volume sufficient to occlude a blood vessel without radially

expanding the blood vessel and to a pre-determined pressure of about 0.5 to about 5.0 atmospheres.

3. The kit of claim 2, further comprising:

a guide catheter having a length and a lumen adapted to access a blood vessel, and having a diameter sufficient to receive a portion of the delivery catheter;

a pressure increasing device adapted to connect to the proximal end of the delivery lumen;

a sensing device adapted to connect to the proximal end of the monitoring cannula to sense one of pressure and fluid flow;

an inflation device adapted to connect to the proximal end of the balloon inflation cannula; and

a guidewire comprising an occlusion device, wherein the guide catheter has a diameter sufficient to receive a portion of the guidewire.

4. The kit of claim 2, further comprising a pressure relief valve coupled to the proximal end of the balloon inflation lumen, and a pressure transferring device comprising a proximal end and a distal end, wherein the distal end is adapted to connect to the proximal end of the delivery lumen.

5. The kit of claim 2, wherein at least one of the delivery lumen and the monitoring cannula is adapted to have a guide wire disposed therethrough to guide the guide catheter through the blood vessel to a region of interest, and wherein the delivery lumen is distal to the monitoring cannula defining at least one of a tapered and a staggered tip.

6. The kit of claim 2, wherein the guide catheter comprises a first convex curved portion; a concave curved portion distal to the first convex curved portion; and a second convex curved portion distal to the concave curved portion.

7. The kit of claim 2, wherein the guide catheter comprises a first guide catheter portion having a first diameter, and a second guide catheter portion

having a second diameter, and the first guide catheter portion and the second guide catheter portion are coaxially and slidingly engaged.

8. The kit of claim 2, wherein the balloon is adapted to inflate to a diameter range of about 2 mm to about 20 mm, wherein the shaft comprises one of a polyether block amide resin having a durometer hardness of about 50 to about 70 shore D, a polyimide, and a polyethylene.

9. The kit of claim 2, further comprising a treatment agent to infuse into the delivery lument, wherein the treatment agent comprises at least one material selected from the group consisting of cells, stem cells, progenitor cells, bone marrow derived progenitor cells, antibodies against CD18, CD11/18, P-selectin, L-selectin, ICAM, VCAM, and TNF, estrogen and estrogen receptor agonists, growth factors, and their isoforms and downstream signaling mediators, heat shock proteins and their downstream signaling mediators, GIK, adenosine and adenosine receptor agonists, NO donors, Na/H exchange inhibitors, Na/K channel openers and their downstream signaling mediators, Ca channel inhibitors, beta-adrenergic receptor inhibitors, alpha-adrenergic receptor inhibitors, free radical scavengers, anti-oxidants, platelet inhibitors, complement system inhibitors, anti-apoptotic drugs, genes that encode the peptides listed above or their ligands, or bio-engineered cells or materials that express the peptides or glycoproteins listed above or their ligands, and mixtures thereof.

10. The kit of claim 3, wherein the pressure increasing device is disposable and is selected from the group consisting of a syringe, a syringe pump, a reciprocating pump, a gear pump, and a centrifugal pump having a removable and disposable rotor and pump housing; and wherein the pressure-sensing device comprises a disposable piezo-electric pressure sensor.

11. The kit of claim 3, wherein the inflation device comprises:  
a large volume syringe comprising an elongated hollow body having a proximal end, a distal end, an opening in the distal end to couple to the proximal exit of the cannula, and a first plunger longitudinally slidable within

the body and having a first shaft with a first piston disposed on the first shaft distal end, the piston and shaft having an elongated hollow inner diameter;

a second plunger longitudinally slidable within the inner diameter and having a second shaft with a second piston disposed on the second shaft distal end;

wherein the inner diameter and second plunger define a low volume syringe having a volume relatively substantially less than a volume of the large volume syringe.

12. The catheter kit of claim 3, wherein the pressure-sensing device further comprises a pressure measurement outlet, and the pressure increasing device further comprises a pressure measurement inlet, and the catheter kit further comprises a connection between the pressure measurement outlet of the pressure-sensing device and the pressure measurement inlet of the pressure increasing device.

13. The catheter kit of claim 2, wherein the balloon comprises at least two materials selected from the group consisting of a polyether block amide resins, polyetheramides, and mixtures thereof;, wherein at least two materials have a Shore D Hardness less than about 70D; and wherein the balloon, upon inflation, has at least one of a conical and a tapered shape.

14. A method comprising:

accessing a vessel selected from the group consisting of external femoral, interior femoral, carotid, jugular, brachial, subclavian, and cephalic with a guide catheter;

accessing a coronary sinus with the guide catheter;

feeding a guidewire with an occlusion device and a retroinfusion balloon catheter to the coronary sinus, great cardiac vein, posterior vein of left ventricle, middle cardiac vein, small cardiac vein, or anterior cardiac vein of right ventricle through the guide catheter;

performing a venogram;

deploying the guidewire and the balloon catheter to one or more targeted vessels;

measuring a baseline parameter in the vein adjacent to a distal end of the balloon catheter;

inflating a balloon at the distal end of the balloon catheter and engaging the occlusion device at a distal end of the guidewire, sufficient to make a pressure waveform in the vein become ventricularized;

after inflating the balloon and after engaging the occlusion device, delivering a liquid comprising at least one of a drug and a treatment agent through the balloon catheter to an outlet port on the balloon catheter distal to the balloon and proximal to the occlusion device.

15. The method of claim 14, further comprising:  
stopping the delivering of the liquid;  
deflating the balloon and disengaging the occlusion device;  
removing the catheter from the vessel; and  
performing an infusate-uptake-enhancing procedure selected from the group consisting of electroporation, ultrasonic excitation, and photodynamic therapy.

16. An apparatus comprising:  
a cannula having a dimension suitable for percutaneous advancement through a blood vessel, the cannula comprising a proximal end and a distal end;

a balloon axially coupled to an exterior surface of the cannula at or adjacent the distal end of the cannula, the balloon comprising a property such that when inflated the balloon will expand in size to an outer diameter sufficient for occlusion of a blood vessel at an inflation pressure less than sufficient to cause an axial force on an inner diameter of the blood vessel and sufficient to cause a radial expansion of the blood vessel.

17. The apparatus of claim 16 wherein the balloon comprises a property such that during inflation and deflation of the balloon, the balloon forms a plurality of radial outer diameters; has a property to cause a post inflation deflated outer diameter of the balloon to retract to within 20 percent of a pre inflated outer diameter of the balloon; and includes a balloon material having

one of a modulus of less than 1.5Mpa, an elongation of at least 500% at breaking, a tension set of less than 30%, and a tension strength of at least 200MPa.

18. The apparatus of claim 16, wherein the balloon comprises one of a first wall thickness at a first axial distance from the distal end of the cannula and a different second wall thickness at a different second axial distance from the distal end of the cannula, and a first pre inflated outer diameter at a first axial distance from the distal end of the cannula and a second pre inflated outer diameter at a second axial distance from the distal end of the cannula such that when inflated the balloon will expand in size to a first outer diameter at a first axial distance from the distal end of the cannula and will expand in size to a different second outer diameter at a different second axial distance from the distal end of the cannula.

19. The apparatus of claim 16, wherein the balloon includes a material comprising one of polyurethane, and a silicone rubber, a styrene-isoprene-styrene tri-block co-polymer with between 50 percent and 100 percent isoprene and between zero percent and 50 percent styrene, a silicone polyether urethane, and an aliphatic polymethane with polydimethyl siloxane backbone; wherein the silicone rubber is vulcanized with amino-mercaptobenzothrazole; and wherein the a styrene-isoprene-styrene tri-block co-polymer includes an additives comprising one of:

thiuram disulfide derivatives ( $R'R''N-(C=5)-S-S-(C=5)-NR'R''$ ),

mercaptobenzothiazoles,

amino-mercaptobenzothrazole,

sulfides, and

azides.

20. A method comprising:  
winding a plurality of layers of ePTFE onto a large mandrel;

bonding a seam between two of a plurality of second ePTFE windings;  
fusing together the layers of ePTFE;  
heating the layers of ePTFE at a temperature of approximately 380 degrees celsius for a duration of between 20 minutes and 30 minutes;  
stretching the fused layers of ePTFE onto a small mandrel, wherein stretching comprises:  
putting the small mandrel within an inner diameter of fused ePTFE layers;  
stretching apart a distal end and a proximate end of the ePTFE sufficiently to stretch the inner diameter of fused ePTFE layers onto an outer diameter of the small mandrel;  
compacting the stretched fused layers of ePTFE axially;  
one of wrapping an outer diameter of the stretched fused layers of ePTFE with a polytetrafluoroethylene, and constraining the outer diameter of the stretched fused layers of ePTFE within a steel tube prior to compacting, and then sufficiently compacting axially inwards a distal end and a proximate end of the stretched fused layers of ePTFE, such that during inflation of the lined ePTFE balloon, the compacted stretched fused layers of ePTFE may not expand axially  
bonding a balloon liner to the compacted stretched fused layers of ePTFE to form a lined ePTFE balloon.

21. An apparatus comprising:

a cannula having a dimension suitable for percutaneous advancement through a blood vessel, the cannula comprising a proximal end and a distal end; and

a filter device having a proximal portion axially coupled to an exterior surface of the cannula at or adjacent the distal end of the cannula, and a distal portion having a first diameter under a first set of conditions and a different second diameter that under a second set of conditions is at least equivalent to an inner diameter of a blood vessel at a region of interest.

22. The apparatus of claim 21, wherein the filter device comprises a property such that under the second condition, the filter device will restrain from flowing through the filter device a plurality of particles having a particle size greater than an average particle size of blood cells and contained in a fluid flowing through the filter device, and will allow aspiration of the plurality of particles from being restrained.

23. The apparatus of claim 21, wherein the filter device comprises a frame portion defined by the proximal portion and the distal portion, and a material stretched on the frame portion to form, under the second condition, a generally conical shaped inner surface, wherein the material has a plurality of openings, each of the plurality of openings having a dimension suitable to allow a fluid to pass therethrough, wherein the frame portion comprises a plurality of longitudinally disposed elements circumferentially spaced and defining a conical shape extending from the proximal portion to the distal portion, and wherein the frame portion comprises a plurality of anchors proximate to the distal portion, each of the plurality of anchors comprising a protruding barb capable of engaging tissue of a blood vessel.

24. The apparatus of claim 21, wherein the filter device has a property such that the first diameter can be transformed to become the second diameter in response to one of at least one tendon coupled to the distal portion of the filter device and the cannula such that actuation of the tendon transforms the distal portion of the filter device from the first diameter to the second diameter, an expansion pressure of between approximately 0.5 atmospheres in pressure and six atmospheres in pressure applied to the generally conical shaped inner surface, a self-expanding frame portion to provide the second set of conditions, at least one balloon coupled to the filter device and the cannula such that inflation of the balloon transforms the distal portion of the filter device from the first diameter to the second diameter.

25. The apparatus of claim 21, wherein the filter device has a property such that the second diameter can be transformed to become the first diameter in response to one of at least one balloon coupled to the filter device and the

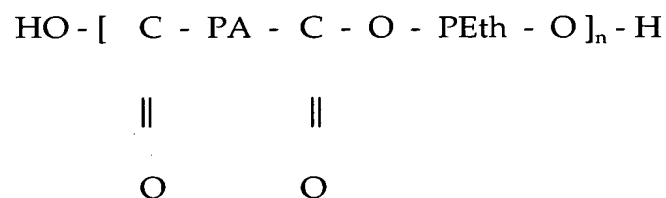


cannula such that deflation of the balloon transforms the distal portion of the filter device from the second diameter to approximately the first diameter, and at least one tendon coupled at the distal portion of the filter device and the cannula such that manipulation of the tendon transforms the distal portion of the filter device from the second diameter to approximately the first diameter.

26. An apparatus comprising:

a cannula having a dimension suitable for percutaneous advancement through a blood vessel, the cannula comprising a proximal end and a distal end;

a balloon axially coupled to an exterior surface of the cannula at or adjacent the distal end of the cannula, the balloon comprising a polymer moiety represented by the formula:



wherein PA represents a polyamide moiety, and PEth represents a polyether moiety, and n represents an integer of at least one.

27. The apparatus of claim 26, wherein the balloon comprises a thermoplastic blend copolymer material having one of a polyether block amide resin moiety and a polyetheramide moiety; comprises a property such that the balloon will inflate to an inflated outer diameter that will occlude a blood vessel and deflate to a post-inflated deflated diameter that will allow the balloon to be withdrawn from the blood vessel; and comprises a property such that the balloon has a pre-inflated volume and a post-inflated deflated volume approximately equal to the pre-inflated volume.

28. The apparatus of claim 26, wherein the balloon comprises a property such that the balloon will have at least 3 wings prior to being inflated and after being deflated,

wherein each wing has a wing length defined by the length of a line extending within the wing along a medial axis of a cross-section of the wing,

wherein a pre-inflated wing length for each wing is approximately equal to a post-inflated deflated wing length of each wing;

wherein each wing has an outer diameter point defined by a point of the wing radially farthest away from an axis of the cannula, and a wing diameter defined by a length of a straight line extending from the axis of the cannula, radially out to the outer diameter point,

wherein a pre-inflated wing diameter for each wing is approximately 30 percent less than a post-inflated deflated wing diameter.

29. The apparatus of claim 26, wherein the balloon comprises a property such that the balloon can achieve a volumetric expansion of greater than about 40% during inflation and can expanded to an inflated outer diameter between 1.5 mm and 18 mm in diameter, will have a double wall thickness between 0.0003 and 0.0038 inches in thickness and a minimum hoop strength of at least about 23,000 psi strength; and will have a durometer hardness of between 50 Shore D and 70 Shore D.

30. An apparatus comprising:

a cannula having a dimension suitable for percutaneous advancement through a blood vessel, the cannula comprising a proximal end and a distal end;

a balloon axially coupled to an exterior surface of the cannula at or adjacent the distal end of the cannula, the balloon comprising a property such that the balloon will inflate to an inflated outer diameter that will occlude a blood vessel and at a predetermined pressure of between 0.5 atmospheres and 5.0 atmospheres of pressure.

31. The apparatus of claim 30, wherein the balloon comprises a property such that the balloon will inflate to one of a predetermined volume and a predetermined inflated outer diameter.

32. The apparatus of claim 30, wherein the balloon comprises a property such that the balloon will inflate to an inflated outer diameter in a range of between 1.25 mm and 18 mm in diameter, and:

at an inflation pressure of 1 atmosphere the balloon will inflate to an inflated outer diameter of approximately 10% of a pre-inflated outer diameter;

at an inflation pressure of 2 atmospheres the balloon will inflate to an inflated outer diameter of at least 20% of the pre-inflated outer diameter;

at an inflation pressure of 3 atmospheres the balloon will inflate to an inflated outer diameter of at least 30% of the pre-inflated outer diameter;

at an inflation pressure of 4 atmospheres the balloon will inflate to an inflated outer diameter of at least 40% of the pre-inflated outer diameter;

at an inflation pressure of 5 atmospheres the balloon will inflate to an inflated outer diameter of at least 50% of the pre-inflated outer; and

at an inflation pressure of 6 atmospheres the balloon will inflate to an inflated outer diameter of least 60% of the pre-inflated outer diameter.

33. An apparatus comprising:

a cannula having a dimension suitable for percutaneous advancement through a blood vessel, the cannula comprising a proximal end and a distal end;

a balloon axially coupled to an exterior surface of the cannula at or adjacent the distal end of the cannula, the balloon comprising a property such that when inflated to a plurality of selected increasing inflation volumes the balloon forms a plurality of predictably increasing radial outer diameters and has an inflation pressure that increases by less than five percent in pressure.

34. The apparatus of claim 33, wherein the plurality of selected increasing inflation volumes increase from 0.05 cubic centimeters to 0.2 cubic centimeters by steps of between 0.005 cubic centimeters and 0.05 cubic centimeters in volume, the inflation pressure of the balloon is between 0.5 atmospheres and 5 atmospheres in pressure, the plurality of predictably increasing outer diameters increase from 2.5 millimeters and 8 millimeters in diameter by steps of 0.25 millimeters in diameter, includes a length of the balloon between 5 millimeters and 10 millimeters in length, and wherein the plurality of

predictably increasing outer diameters are equally spaced increments in diameter of between 0.2 millimeter and 0.4 millimeter increase in diameter.

35. The apparatus of claim 33, wherein the balloon material is at least one of a styrene isoprene styrene (SIS), styrene butadiene styrene (SBS), styrene ethylene butylene styrene (SEBS), polyetherurethane, ethyl propylene, ethylene vinyl acetate (EVA), ethylene methacrylic acid, ethylene methyl acrylate, and ethylene methyl acrylate acrylic acid.

36. An apparatus comprising:

a cannula having a dimension suitable for percutaneous advancement through a blood vessel, the cannula comprising a proximal end and a distal end;

a balloon axially coupled to an exterior surface of the cannula at or adjacent the distal end of the cannula, the balloon comprises a property such that when inflated to a first inflation volume, the balloon has a first inflated axial length and an outer diameter of the balloon exerts a first inflation pressure on an inner diameter of a blood vessel sufficient to occlude the blood vessel at a region of interest, and when inflated to a second greater inflation volume, the balloon has a second inflated axial length that is sufficiently greater than the first inflated axial length to allow the outer diameter of the balloon to exert a second inflation pressure that is less than five percent greater than the first inflated pressure on the inner diameter.

37. The apparatus of claim 36, wherein the balloon has a pre-inflated outer diameter of between 1 millimeter and 3 millimeters in diameter, an inflated outer diameter between 2 millimeters and 20 millimeters at an inflation pressure of between 0.5 atmosphere and 4 atmospheres in pressure, and an inflated axial length that increases with increasing inflation volume to allow the balloon to occlude the blood vessel while the balloon inflated outer diameter maintains an inflation pressure of between 3 atmosphere and 4 atmospheres pressure on an inner diameter of the blood vessel; and wherein the balloon material is at least one of a styrene isoprene styrene (SIS), styrene

butadiene styrene (SBS), styrene ethylene butylene styrene (SEBS), polyetherurethane, ethyl propylene, ethylene vinyl acetate (EVA), ethylene methacrylic acid, ethylene methyl acrylate, and ethylene methyl acrylate acrylic acid.

38. The apparatus of claim 36, wherein the balloon has a pre-inflated outer diameter of between 0.025 inches and 0.065 inches in diameter, a pre-inflated length of between 2 millimeters and 30 millimeters in length, and a pre-inflated wall thickness of between 0.002 inches and 0.02 inches in thickness, has an inflated outer diameter of between 1.25 millimeters and 12 millimeters in diameter, and a wall thickness that decreases by between ten percent and 75 percent in thickness at an inflation pressure of between 3 atmosphere and 4 atmospheres in pressure.

39. The apparatus of claim 36, wherein the cannula functions as one or more of a guide catheter, a delivery catheter, and a guidewire catheter; and wherein the axial coupling of the balloon to the cannula includes shrink tube bonding the balloon to a cannula such that an exterior surface of the balloon forms a symmetrical shape with respect to an axis of the cannula when the balloon is inflated over a range of inflation volumes.

40. An apparatus comprising:

- a cannula having an outer diameter less than 0.090 inches, a proximal end, and a distal end;

- a balloon axially coupled to an exterior surface of the cannula at or adjacent the distal end of the cannula, the balloon comprising a property such that when inflated to a selected inflation volume the balloon will expand in size to an outer diameter sufficient to occlude the blood vessel; and

- an infusion lumen having an inner diameter greater than 0.010 inches extending from the proximal end to the distal end of the cannula and exiting an infusion opening distal to the balloon;

- an accessory lumen extending from the proximal end to the distal end of the cannula and exiting an accessory opening distal to the balloon;

wherein at least one of the infusion lumen and the accessory lumen is adapted to have a guide wire disposed therethrough to guide the cannula through the blood vessel to a region of interest.

41. The apparatus of claim 40, wherein the cannula has a dimension suitable to be received within a guide catheter having an outer diameter in a range between 5 French and 9 French the accessory lumen has an inner diameter that is less than the inner diameter of the infusion lumen, and the cannula has a shaft having an outer diameter less than 0.060 inches.

42. The apparatus of claim 40, wherein the balloon comprises a property such that the balloon has an inflation pressure of less than five atmospheres of pressure at the selected inflation volume, the balloon comprises a property such that when inflated to a plurality of increasing inflation volumes the balloon forms a plurality of increasing radial outer diameters and has an inflation pressure that increases by less than five percent in pressure, and the balloon will expand in size to an outer diameter in a range of between 1 millimeter and 15 millimeters in diameter controlled by volume injection of one of a gas and a fluid.

43. The apparatus of claim 40, wherein the cannula further includes a balloon inflation lumen extending from the proximal end of the cannula to the balloon; wherein the accessory lumen extends a first length, the infusion lumen extends a second length, and the inflation lumen extends a third length in distance beyond the proximal end of the cannula, and at least one of the first, second and third length is a different distance in length; and wherein the accessory lumen has a dimension suitable to infuse a first volume of treatment agent to the region of interest; and the balloon inflation lumen has a dimension suitable to inflate the balloon with a volume of one of a gas and a liquid to an inflation pressure of less than six atmospheres.

44. The apparatus of claim 40, wherein at least one of the accessory lumen, the infusion lumen, and the inflation lumen are attached to a luer adapter at the proximal end of the cannula, and the luer adapter includes:

an infusion port having a spring-loaded pressure seal; and  
a balloon inflation port having a syringe.

45. The apparatus of claim 40, wherein the accessory lumen has a dimension suitable to allow on of a device to be coupled to a proximal end of the accessory lumen and a device to be disposed through the accessory lumen to measure of one of CRF, EKG, O<sub>2</sub> level, pressure, flow, blood sampling, and temperature at the region of interest; wherein the infusion lumen and the accessory lumen each include one of a reinforcing mandrel disposed within the cannula and extending from the proximal end of the cannula to the balloon, a braid reinforced polymer tube, and a coil reinforced polymer tube; and, wherein at least one of the infusion lumen and the accessory lumen is adapted to receive the guide wire, have the guide wire disposed therein and exiting a proximal opening at the proximal end of the cannula such that the cannula can be used in an over-the-wire fashion, and have the guide wire removed therefrom.

46. The apparatus of claim 40, wherein the cannula further comprises a support mandrel disposed within the cannula and extending from the proximal end of the cannula to the balloon, and the support mandrel has one of a constant outer diameter of less than 0.017 inches in diameter, and a proximal outer diameter of less than 0.017 inches in diameter and steps down to a plurality of lesser outer diameters to a distal diameter of between 0.012 inches and 0.003 inches in diameter.

47. The apparatus of claim 46, wherein the support mandrel is anchored to at least one of a proximal adapter at the proximal end of the cannula and the cannula where the balloon is coupled to the exterior surface of the cannula.

48. An apparatus comprising:  
a cannula having a proximal end, and a distal end;  
a balloon axially coupled to an exterior surface of the cannula at or adjacent the distal end of the cannula, the balloon comprising a property such

that when inflated the balloon will expand in size to an outer diameter sufficient to occlude the blood vessel at a region of interest;

a guidewire tube extending from the proximal end to the distal end of the cannula and exiting a guidewire opening in the distal end of the cannula;

an infusion tube around the guidewire tube extending from the proximal end to the distal end of the cannula and exiting an infusion opening in the distal end of the cannula;

an inflation lumen defined between the infusion tube and the cannula;

wherein the guidewire tube, infusion tube, and inflation lumen are co-axially aligned with an axis of the cannula.

49. The apparatus of claim 48, wherein the inflation lumen extends from the proximal end of the cannula to the balloon and has a dimension suitable to inflate the balloon, the infusion tube has an outer diameter sufficient to infuse a treatment agent to the region of interest distal to the balloon, and the guidewire tube has a sufficient outer diameter and is adapted to have a guide wire disposed therethrough to guide the cannula through the blood vessel to a region of interest.

50. The apparatus of claim 48, wherein the guidewire tube, the infusion tube, and the inflation lumen have a circular cross sectional shape with respect to an axis of the cannula; wherein the cannula exterior surface has a circular cross sectional shape with respect to an axis of the cannula where the balloon is axially coupled to the exterior surface of the cannula; and wherein the infusion tube is coupled to the exterior surface of the guidewire tube at a location distal to the balloon.

51. An apparatus comprising:

a cannula having a proximal end, and a distal end;

a balloon axially coupled to an exterior surface of the cannula at or adjacent the distal end of the cannula, the balloon comprising a property such that when inflated the balloon will expand in size to an outer diameter sufficient to occlude the blood vessel at a region of interest;



a guidewire tube extending from the proximal end to the distal end of the cannula and exiting a guidewire opening in the distal end of the cannula, the guidewire tube co-linearly or co-axially aligned with an axis of the cannula;  
an infusion lumen defined between the guidewire tube and the cannula;  
an inflation tube extending from the proximal end of the cannula to the balloon, the inflation tube co-linearly aligned with an axis of the cannula.

52. The apparatus of claim 59, wherein the infusion lumen is co-linearly or co-axially aligned with the cannula; and wherein the inflation tube extends from the proximal end of the cannula to the balloon and has a dimension suitable to inflate the balloon, the infusion lumen has a dimension sufficient to infuse a treatment agent to the region of interest distal to the balloon, and the guidewire tube has a sufficient outer diameter and is adapted to have a guide wire disposed therethrough to guide the cannula through the blood vessel to a region of interest.

53. The apparatus of claim 59, wherein the guidewire tube and the infusion lumen have a circular cross sectional shape with respect to an axis of the cannula; wherein the cannula exterior surface has a circular cross sectional shape with respect to an axis of the cannula where the balloon is axially coupled to the exterior surface of the cannula; and wherein the infusion tube is attached to the exterior surface of the guidewire tube at a location distal to the balloon.

54. An apparatus to inflate a low volume balloon to occlude a blood vessel, the balloon coupled to a distal end of a cannula having an inflation lumen extending from the balloon to a proximal end of the cannula and through a proximal exit in the cannula, the apparatus comprising:

a large volume syringe comprising an elongated hollow body having a proximal end, a distal end, an opening in the distal end to couple to the proximal exit of the cannula, and a first plunger longitudinally slidable within the body and having a first shaft with a first piston disposed on the first shaft distal end, the piston and shaft having an elongated hollow inner diameter;

a second plunger longitudinally slidable within the inner diameter and having a second shaft with a second piston disposed on the second shaft distal end;

wherein the inner diameter and second plunger define a low volume syringe having a volume relatively substantially less than a volume of the large volume syringe.

55. The apparatus of claim 54, further comprising a first lock mechanism to releasably secure the first plunger to lock the first piston at at least one location along the hollow body, a second lock mechanism to releasably secure the second plunger to lock the second piston at at least one location along the hollow inner diameter, and at least one latch mechanism to unlatch the second lock mechanism from the hollow inner diameter to move the second piston towards the proximal end of the hollow body to evacuate a selected volume of fluid from the balloon into the low volume syringe.

56. The apparatus of claim 55, wherein the second lock mechanism includes an adjustment mechanism to adjust the position of the second piston to at at least one location along the hollow inner diameter; and wherein the adjustment mechanism includes a threaded cavity coupled to a knob exterior to the large volume syringe and a bolt portion threadably engaging the cavity and coupled to the second plunger such that the second piston may be adjusted to at at least one location along the hollow inner diameter by rotating the knob.

57. The apparatus of claim 56, wherein rotation of the knob from a first position to a balloon volume position delivers a selected volume of fluid to the balloon, and rotation of the knob from the balloon volume position back to the first position evacuates a selected volume fluid from the balloon into the low volume syringe.

58. An apparatus comprising:  
a cannula having a proximal end, and a distal end;  
a balloon axially coupled to an exterior surface of the cannula at or adjacent the distal end of the cannula, the balloon comprising a property such

that when inflated to a selected inflation volume the balloon will expand in size to an outer diameter sufficient to occlude the blood vessel at a region of interest;

a lumen extending from the proximal end to the distal end of the cannula and exiting an opening in the cannula distal to the balloon;

at least one hole through the exterior surface of the cannula and to the lumen at a location proximal to the balloon to allow perfusion of a blood and/or a treatment agent between a location in the blood vessel proximal to the balloon and the region of interest.

59. The apparatus of claim 58, further including a guidewire disposed through lumen and slidably adjustable such that a distal end of the guidewire can be extended past the at least one hole; wherein guidewire lumen has an inner diameter and the guidewire has an outer diameter sufficient in diameter to occlude the guidewire lumen; and wherein the at least one hole includes between four and eight holes and the guidewire has a dimension to be slidably adjustable to extend or retract a distal end of the guidewire to a location past none or any of the holes.

60. The apparatus of claim 58, wherein the at least one hole includes a plurality of holes having different sizes to perfuse blood at a flow rate of between a full flow and a plurality of fractions of the full flow, the different sizes increase in size from a most distal hole to a most proximate hole, and the holes are oriented longitudinally with respect to an axis of the cannula.

61. A method comprising:

advancing a cannula percutaneously through a blood vessel to a region of interest, the cannula having a proximal end, a distal end, and an exterior surface at or adjacent the distal end of the cannula axially coupled to a balloon,

inflating the balloon from a first diameter to a different second diameter that is at least equivalent to an inner diameter of a blood vessel to occlude the blood vessel at the region of interest;

infusing a treatment agent to the region of interest distal to the balloon;

perfusing a blood and/or a treatment agent flow between a location in the blood vessel proximal to the balloon and the region of interest.

62. The method of claim 61, wherein perfusing includes:

perfusing blood and/or treatment agent via a lumen extending through the cannula from a location proximal to the balloon to a location distal to the balloon, via a proximal hole through the exterior surface of the cannula and to the lumen at a location proximal to the balloon, and a distal hole through the exterior surface of the cannula and to the lumen at a location distal to the balloon.

63. The method of claim 61, wherein inflating includes inflating the balloon for a first period of time and perfusing includes deflating the balloon for a second period of time; and at least one more repetition of inflating, infusing, and deflating.

64. The method of claim 61, wherein perfusing includes:

retracting back a guidewire disposed through a guidewire lumen extending from the proximal end to the distal end of the cannula and exiting an opening in the cannula distal to a balloon, for a first period of time;

wherein retracting includes retracting a distal end of the guidewire from a location distal to at least one hole from the guidewire lumen through the exterior surface of the cannula and proximal to the balloon to a location proximal to the at least one hole.

65. The method of claim 64, further comprising advancing the guidewire to a location distal to the at least one hole to prohibit a blood and/or a treatment agent perfusion between a location in the blood vessel proximal to the balloon and the region of interest, for a second period of time, and repeating infusing, retracting and advancing at least once more.

66. The method of claim 64, wherein retracting includes retracting a distal end of the guidewire to control an amount of a blood and/or a treatment agent perfusion between a location in the blood vessel proximal to the balloon and

the region of interest by adjusting the guidewire to extend or retract a distal end of the guidewire to a location amongst a plurality of the at least one hole to allow a blood and/or a treatment agent to perfuse between the holes and the lumen at a selected perfusion rate.

67. The method of claim 61, wherein infusing includes infusing a volume of a progenitor cell suspension including bone marrow-derived progenitor cells.

68. The method of claim 61, wherein inflating includes:  
increasing an axial length of the balloon;  
maintaining the inflation pressure on the inner diameter of the blood vessel.

69. An apparatus comprising:  
a cannula having a proximal end, and a distal end;  
a balloon axially coupled to an exterior surface of the cannula at or adjacent the distal end of the cannula, the balloon comprising a property such that when inflated to a selected inflation volume the balloon will expand in size to an outer diameter sufficient to occlude the blood vessel at a region of interest;

the cannula having a lumen having a proximal end at a location proximal to the balloon and extending to a distal end at a location distal to the balloon, a proximal hole through the exterior surface of the cannula and to the lumen at a location proximal to the balloon, and a distal hole through the exterior surface of the cannula and to the lumen at a location distal to the balloon.

70. The apparatus of claim 69, wherein the lumen, the proximal hole and the distal hole have a dimension suitable to allow perfusion of a blood and/or a treatment agent between a location in the blood vessel proximal to the balloon and the region of interest, and the proximal hole has a selected diameter and the distal hole has a selected diameter to control an amount of a blood and/or a treatment agent to perfuse between the selected holes and the lumen.

71. The apparatus of claim 69, wherein the cannula further comprises one of an infusion lumen extending from the proximal end of the cannula to a infusion exit through the exterior surface of the cannula at a location proximal to the balloon to deliver treatment agent to the blood vessel proximal to the balloon, and an infusion lumen extending from the proximal end of the cannula to a infusion exit through the exterior surface of the cannula at a location distal to the balloon to deliver treatment agent to the blood vessel distal to the balloon.

72. The apparatus of claim 69, wherein the cannula further comprises a first infusion lumen extending from the proximal end of the cannula to a infusion exit through the exterior surface of the cannula at a location proximal to the balloon to deliver treatment agent to the blood vessel proximal to the balloon, and a second infusion lumen extending from the proximal end of the cannula to a infusion exit through the exterior surface of the cannula at a location distal to the balloon to deliver treatment agent to the blood vessel distal to the balloon.

73. The apparatus of claim 69, further comprising:

a proximal balloon axially coupled to an exterior surface of the cannula proximal to the balloon, the proximal balloon comprising a property such that when inflated to a selected inflation volume the balloon will expand in size to an outer diameter sufficient to occlude the blood vessel proximal to the a region of interest;

wherein the cannula further comprises a first infusion lumen extending from the proximal end of the cannula to a first exit through the exterior surface of the cannula at a location between the balloon and the proximal balloon to deliver treatment agent to the region of interest, and a second infusion or pressure sensing lumen extending from the proximal end of the cannula to a second exit through the exterior surface of the cannula at a location between the balloon and the proximal balloon to deliver treatment agent to or sense pressure at the region of interest.

74. A catheter comprising:

a shaft comprising a proximal end and a distal end, and defining a delivery lumen through a portion thereof, the delivery lumen comprising a proximal end and a distal end;

a delivery port coupled to the distal end of the delivery lumen;

a pressure monitoring lumen, a portion of the pressure monitoring lumen disposed within the shaft, comprising a proximal end and a distal end;

a pressure port coupled to the distal end of the pressure monitoring lumen;

a balloon inflation lumen, a portion of the balloon inflation lumen disposed within the shaft, comprising a proximal end and a distal end;

a balloon adjacent to the distal end of the flexible shaft, the balloon comprising at least one material selected from the group consisting of polyether block amide resins, blends of polyether block amide resins, a composite including an elastomeric material and EPTFE, a styrene-isoprene-styrene tri-Block co-polymer, and blends and mixtures thereof;

wherein the balloon is adapted to inflate to at least an elasticity of about 40% at a pre-determined gauge pressure of about 0.5 to about 6.0 atmospheres;

a balloon inflation port within the balloon and coupled to the distal end of the balloon inflation lumen;

wherein at least one of the delivery lumen and pressure monitoring lumen are adapted to receive a guidewire.

75. The catheter of claim 74, wherein the delivery lumen is distal to the pressure monitoring lumen defining at least one of a tapered and a staggered tip, and the delivery lumen is adapted to receive the guidewire; or wherein the pressure monitoring lumen is distal to the delivery lumen defining at least one of a tapered and a staggered tip, and the pressure monitoring lumen is adapted to receive the guidewire.

76. A catheter comprising:

a shaft comprising a proximal end and a distal end and defining a delivery lumen through a portion thereof, the delivery lumen comprising a proximal end and a distal end;

a delivery port coupled to the distal end of the delivery lumen;

a pressure monitoring lumen comprising a proximal end and a distal end, a portion of the pressure monitoring lumen disposed within the flexible shaft;

a pressure port coupled to the distal end of the pressure monitoring lumen;

a balloon inflation lumen comprising a proximal end and a distal end, a portion of the balloon inflation lumen within the flexible shaft;

a balloon adjacent to the distal end of the flexible shaft, the balloon comprising at least one material selected from the group consisting of polyether block amide resins, blends of polyether block amide resins, a composite including an elastomeric material and EPTFE, a styrene-isoprene-styrene tri-Block co-polymer, and blends and mixtures thereof;

a balloon inflation port coupled to the distal end of the balloon inflation lumen and the balloon inflation port within the balloon;

wherein a first wall thickness of the balloon adjacent a proximal end of the balloon is smaller than a second wall thickness of the balloon adjacent a distal end of the balloon; and

wherein upon inflation, a first diameter of the balloon adjacent to a proximal end of the balloon is larger than a second diameter adjacent a distal end of the balloon.

77. The catheter of claim 76, wherein the balloon, upon inflation, has one of a tapered balloon shape, and a conical balloon shape.

78. A catheter comprising:

a shaft comprising a proximal end and a distal end, and defining a delivery lumen through a portion thereof, the delivery lumen comprising a proximal end and a distal end;

a delivery port coupled to the distal end of the delivery lumen;

a pressure monitoring lumen, a portion of the pressure monitoring lumen disposed within the shaft, comprising a proximal end and a distal end;

a pressure port coupled to the distal end of the pressure monitoring lumen;



a balloon inflation lumen, a portion of the balloon inflation lumen disposed within the shaft, comprising a proximal end and a distal end;

a balloon adjacent to the distal end of the flexible shaft, the balloon comprising at least one material selected from the group consisting of polyether block amide resins, blends of polyether block amide resins, a composite including an elastomeric material and EPTFE, a styrene-isoprene-styrene tri-Block co-polymer, and blends and mixtures thereof;

a balloon inflation port within the balloon and coupled to the distal end of the balloon inflation lumen;

wherein the delivery lumen is distal to the pressure monitoring lumen defining at least one of a tapered and a staggered tip, and the delivery lumen is adapted to receive the guidewire.